MAR 3 1 2004

510(K) SUMMARY

K033702
page 1 of 2

Name of Firm: Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, MA 01104

510(k) Contact: Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance

Trade Name: Blackstone™ PEEK Vertebral Body Replacement System

Common Name: Spinal Vertebral Body Replacement Device

Device Product Code & Classification: **MQP**– 888.3060 – Spinal Vertebral Body Replacement Device

Substantially Equivalent Devices: Blackstone Surgical Mesh System (K030744)

Device Description:

Blackstone Medical, Inc. PEEK Vertebral Body Replacement (VBR) System is comprised of a variety of components fabricated and manufactured from Polyetheretherketone (PEEK Optima LT) as described by ASTM F-2026. This material is utilized due to its radiolucent properties, which aid the surgeon in determining if fusion in the operative site has occurred. Titanium markers are inserted into components to give surgeons a visual aid in determining the location of the implant both inter and postoperatively. The superior and inferior surfaces of the construct have a pattern of ripples to provide increased stability and help prevent lateral movement of the device.

K033708
page 2 of 2

Intended Use / Indications for Use:

The Blackstone Medical PEEK Vertebral Body Replacement System is indicated for use in the thoraco-lumbar spine (T1-L5) to replace a deseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The PEEK VBR System is also indicated for treating fractures of the thoracic and lumbar spine. It is recommended that bone graft material be packed inside the system prior to implantation. The PEEK VBR System is intended to be used with supplemental internal fixation. Specifically, the supplemental internal fixation system that may be used with the PEEK VBR System is the Blackstone Medical Spinal Fixation System.

Basis of Substantial Equivalence:

By its very nature, the Blackstone™ PEEK Vertebral Body Replacement System is substantially equivalent to the Blackstone Surgical Titanium Mesh System (K030744), which has been cleared by FDA for use in patients with tumor, trauma or fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Mr. Dean E. Ciporkin:
Director, Regulatory Affairs and Quality Assurance
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K033702
Trade/Device Name: Blackstone™ PEEK Vertebral Body Replacement System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: February 26, 2004
Received: February 26, 2004

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): #K033702

Device Name: Blackstone PEEK Vertebral Body Replacement System

Indications For Use:

The Blackstone VBR device is indicated for use in the thoraco-lumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Blackstone VBR device is also indicated for treating fractures of the thoracic and lumbar spine.

The Blackstone VBR device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the VBR device is intended to be used with bone graft.

The Blackstone VBR device is intended for use with supplemental internal fixation. The supplemental internal fixation system that may be used is the Blackstone Spinal Fixation System.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhran

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K033702